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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,269	02/08/2002	Raymond E. Ideker	5656-21	9014

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/071,269	IDECKER ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-48* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-46) in the reply filed on January 18, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claim 12 is objected to because of the following informalities: the reference to "said time" on line 6 lacks antecedent basis. The examiner will assume applicant intended to refer to a time associated with the determination of a cardiac arrhythmia. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant argues in the Remarks that his newly worded limitation concerning the administration of a therapeutic drug selected from the group consisting of a calcium channel blocker, a calmodulin blocker, and a calmodulin kinase inhibitor, *and* a first antiarrhythmic drug, relates to the application of a combination of drugs (i.e., one of a calcium channel blocker, calmodulin blocker, or a calmodulin kinase inhibitor, *and* a first antiarrhythmic drug). The examiner cannot find in the original specification, however, where the applicant describes the administration of not only the blocker or inhibitor drugs in combination with a first antiarrhythmic drug, but also in combination with a third drug (i.e., the second antiarrhythmic drug).

Claim Rejections - 35 USC § 102 and § 103

5. As the current examiner does not have access to the previous examiner's Office Action on the Patent Office's central server, and for the sake of brevity, the examiner will simply refer the applicant back to the previous Office Action for a detailed discussion of the following art rejections, with full faith and credit given to the previous examiner as per MPEP section 704.01.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 6, 12, 17 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Elsberry et al. (Pat. No. 5,662,689).

8. Claims 12, 14, 15, 19, 21-25, 27, 34, 35, 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (Pat. No. 5,925,066).

9. Claims 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Buscemi et al. (Pat. No. 5,690,682).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 2, 3 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (Pat. No. 5,662,689).

12. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (Pat. No. 5,662,689) in view of Anderson et al. (Pat. No. 6,518,245).

13. Claims 16, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. in view of Anderson et al. (Pat. No. 6,519,245).

14. Claims 20, 28, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (Pat. No. 5,925,066).

15. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi et al. (Pat. No. 5,690,682) in view of Anderson et al. (Pat. No. 6,518,245).

Response to Arguments

16. Applicant's arguments filed January 18, 2005 have been fully considered but they are not persuasive.

Regarding the rejection of claims 1, 5, 6, 12, 17 and 18 under Elsberry et al., the applicant argues that Elsberry et al. apply pain alleviating drug therapy but do not disclose applying a calcium channel blocker, a calmodulin blocker, or a calmodulin kinase inhibitor in combination with an antiarrhythmic drug. The examiner responds that claim 1 does not require that such a combination of drugs be applied. The term *a therapeutic drug* does not necessitate that a plurality of drugs be combined and applied. The examiner further considers an antiarrhythmic drug to be a therapeutic drug. Even if the applicants were to reword the claim to mimic the language relied upon in the Remarks, the examiner would consider Elsberry et al. to still read on the claimed invention. As stated in col. 15, lines 23-41, a combination of therapeutic drugs may be dispensed including drugs that lower the defibrillation threshold, and drugs such as calcium channel blockers that reduce pain (the examiner notes that the applicant states that such drugs may be used to relieve and control angina pectoris at the bottom of page 7). A concoction of drugs that not only reduces pain but also reduces the defibrillation threshold is still considered to be a combination of drugs in an amount effective to decrease the strength of the required shock.

Regarding the rejection of claims 12, 14, 15, 19, 21-25, 27, 34, 35, 37 and 39 under Kroll et al., the applicant argues that Kroll et al. do not disclose a device to decrease the strength of the shock, nor methods of using such a device. Apparatus claim 12 does not require such a narrow interpretation of the prior art. Statements of

intended use for the controller and the injector (i.e., "...so that the strength of said shock is decreased..." and "...to administer a therapeutic drug selected from the group consisting of...") fail to saliently distinguish over the apparatus of the Kroll et al. reference. A proper reading of the claim doesn't even require a cardiac device containing the specific drug or combination of drugs listed –only an injector *operative to administer* such a drug(s). As disclosed, the injector of Kroll et al. is clearly capable of administering therapeutic drugs and combinations thereof. Furthermore, the applicant's amendment involving a controller "...configured to deliver said therapeutic drug at said time with said therapeutic electric shock..." fails to read over the apparatus of the Kroll et al. device. The examiner considers the Kroll et al. device to have such a configuration as evidenced by the text abridging cols. 4 and 5. At the time of an occurring arrhythmia, the controller is configured to issue a therapeutic electric shock with a therapeutic drug. The word *with* does not connote *concurrently*, but merely in relatively close time association.

Concerning the rejection of claims under Buscemi et al., the applicants state that Buscemi et al. does not disclose a drug delivery system that can include a therapeutic shock as recited in claim 41. Buscemi et al. disclose a system that can apply electrical therapy to revert arrhythmias as per col. 4, lines 42-56. Buscemi et al. also teach that defibrillation may be used in conjunction as per col. 6, lines 1-14, and takes steps to protect the electrical circuitry from possible damage resultant from such high energy shocks. The applicant's assertion that Buscemi et al. fail to anticipate that the level of shock is decreased as compared to the shock required to treat an arrhythmia in the absence of administration of the calcium channel blocker and other drugs, is not agreed with. The language referred to is considered a recitation of desired result and would inherently be met by any system incorporating the same anti-arrhythmic drugs employed by the applicant (note col. 6, lines 51-58).

Regarding the rejection of claims 2, 3 and 7-10 under Elsberry et al., the same arguments presented above when discussing the Elsberry et al. reference with respect to claims 1, 5, 6, 12, 13, 17 and 18 apply here as well. Furthermore, the applicant states that claim 7 is distinguished from the prior art in that it recites a method step that

requires less energy than the typical 34 Joules normally used to revert arrhythmias by the prior art. The examiner responds that claim 7 does not preclude devices that output a standard 34 Joules. The claim simply requires a pulse of not greater than 34 Joules. A pulse of 34 Joules is not greater than 34 Joules. In any event, since the system of Elsberry et al. is designed to reduce the defibrillation threshold, it should be self-evident that less energy than normal would be required to revert the arrhythmia. Regarding the various percentages recited in claims 8-10 and the particular parameter of the shock pulse modified to reduce the energy of the pulse, the particular percentage of defibrillation shock threshold reduction incurred by drug therapy would clearly have been considered a matter of obvious design dependent upon the individual under treatment, the patient's tolerance to drug therapy, possible side-effects related to drug dosages, effectiveness of the various drugs, defibrillator design and output power, etc.

Regarding the rejection of claim 4, whether the calmodulin blocker is a CaM kinase inhibitor or not is immaterial since the applicant has not limited the base claim to the administration of such a drug. The application of a calmodulin blocker is optional – not mandatory.

Regarding claim 11, the examiner considers the dosage of calcium channel blocker necessary to noticeably reduce pain to also be of an amount effective to inhibit a delayed afterdepolarization caused by a shock.

Regarding claims 29-33 note the rejection of these claims under §112, 1st paragraph above.

Regarding the rejection of claims 16, 26 and 38 under Kroll et al. in view of Anderson et al., despite the applicant's conclusory statement that neither Kroll et al. nor Anderson et al. either alone or in combination teach or suggest the limitations cited therein, the base claims from which these claims depend do not even require the particular drugs set forth. Claim 12 from which claim 16 depends, for example, merely requires an injector *to administer* a therapeutic drug and not the drug or drugs themselves. Further limitations on a non-element of the invention (i.e., the drug(s)) in subsequent claims will have little effect on overcoming any reference that has an injector capable of administering therapeutic drugs. In addition, the reduction of shock

strength that the applicant is apparently relying on to distinguish over the prior art is merely a statement of desired result. Furthermore, even if one were to give weight to the desired result, one can argue that the administration of a drug (any drug) to successfully revert an arrhythmia would inherently reduce the necessary shock strength to zero (i.e., a subsequent shock wouldn't be required).

Regarding the rejection of claims 20, 28, 36 and 40, the applicant refers back to previously mentioned reasons for allowance. The examiner also in kind refers back to previously mentioned reasons for rejection. The applicant further states that external devices are patentably distinct from internal devices because internal devices exclude defibrillators like those used by emergency rescuers. Examiner Hsu, who had drafted the previous Office Action, specifically informed the applicant's representative during a telephone conversation on September 21, 2004 that several species were noted including those directed to internal and external configurations, but that such species were not considered to be patentably distinct (see par. 6 of the prior Office Action). It was further stated that upon discovery of one of the species in the prior art, the other related species would be considered an obvious variant under §103. If the applicant considered the internal species to be distinct from the external species, an election of one of the alleged patentably distinct species should have been made at that time, with the other species withdrawn from consideration. In any event, the applicant's line of reasoning to establish distinctness is not convincing. The two species are not patentably distinct simply because one embodiment would exclude external defibrillators. The injection of drugs externally through hypodermic needles is old and well-known as are external defibrillators. Once given the teaching that an implantable device can administer electrical cardiac therapy in conjunction with drug therapy, those of ordinary skill in the art would have seen the obvious implications of extending such a treatment to externally applied cardiac therapy systems. The applicants have not given any reasoning as to why one of ordinary skill in the art would not expect the external injection of therapeutic drugs to have similar effects to the internal injection of similar drugs with respect to electrical therapy.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
May 16, 2005

KENNEDY SCHAETZLE
PRIMARY EXAMINER